IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of : Attorney Docket No. 2005_0470A

Daisuke ITOH et al. : Confirmation No. 6230

Serial No. 10/528,229 : Group Art Unit 1782

Filed March 18, 2005 : Examiner Ellen S. Wood

STRONGLY STRETCHED ALIPHATIC : Mail Stop: APPEA

POLYESTER MOLDINGS

TIC : Mail Stop: APPEAL BRIEFS-PATENTS

APPEAL BRIEF FILED UNDER 37 CFR §41.37

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

The following is Appellants' Brief, submitted under the provisions of 37 CFR § 41.37.

Pursuant to the provisions of 37 CFR § 41.20, this brief is submitted with a fee of \$540.00.

I. REAL PARTY IN INTEREST

The real party in interest is KUREHA CORPORATION, the assignee of record (Reel/Frame: 017423/0906).

II. RELATED APPEALS AND INTERFERENCES

There are no related prior or pending appeals, interferences or judicial proceedings known to Appellants, Appellants' legal representative, or assignee, which may be related to, directly affect or be directly affected by, or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

The status of the claims is as follows:

Pending claims: 1-7 and 10-12

Rejected claims: 1-7 and 10-12

Cancelled claims: 8 and 9

Withdrawn claims: None

Appealed claims: 1-7 and 10-12

A complete copy of all the pending claims is provided in the attached Claims Appendix.

IV. STATUS OF AMENDMENTS

Claim 1 was amended, and claim 9 was cancelled, in the response filed August 17, 2010, subsequent to the final Office Action of May 17, 2010. The Examiner indicated that these claim amendments will be entered for purposes of appeal, in the Advisory Action of September 16, 2010.

V. <u>SUMMARY OF CLAIMED SUBJECT MATTER</u>

A concise explanation of the subject matter of the independent claim involved in the appeal is presented below. All references to the specification refer to the specification filed on March 18, 2005.

Claim 1 is directed to a stretched product of crystalline aliphatic polyester, having a crystal melting point higher by at least 3°C than that of an unstretched product thereof, wherein said crystalline aliphatic polyester is glycolic acid homopolymer, and wherein the stretched product is obtainable by stretching the glycolic acid homopolymer at 45-60°C at a stretching ratio exceeding 3×3 times.

Support for this claim language is found on page 4, lines 16-20, page 6, lines 19-23, page 7, lines 15-16, and page 15, line 17 to page 16, line 6 of Appellants' specification.

VI. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1-7 and 10-12 are unpatentable under 35 U.S.C. § 103(a) based on Shiiki et al. (EP 0925915) in view of Kawakami et al. (U.S. 6,159,416).

VII. ARGUMENT

The rejection of claims 1-7 and 10-12 under 35 U.S.C. § 103(a) as being unpatentable over Shiiki et al. (EP 0925915) in view of Kawakami et al. (U.S. 6,159,416) is respectfully traversed.

The Position of the Examiner

The position of the Examiner, as described in the final office action of May 17, 2010, and the Advisory Action of September 16, 2010, is as follows.

The Examiner takes the position that Shiiki et al. disclose a gas barrier multi-layer hollow container with a polyglycolic acid layer, wherein the blow molding process to make the hollow container includes a stretch blow molding process. The Examiner asserts that the container has a layer that is a stretched product of crystalline aliphatic polyester.

The Examiner admits that Shiiki et al. do not disclose that the aliphatic polyester has a crystal melting point higher by at least 3°C and 5 °C than that of an unstretched product (Appellants' claims 1-7 and 9-12), or a sub-dispersion peak temperature of at least -46°C (Appellants' claims 3, 4, 5, 7, 10, 11 and 12), or a main dispersion peak temperature of at least 67°C (Appellants' claims 4, 6, 7, 10, 11 and 12), or an orientation degree of at least 83% as measured by wide-angle X-ray diffractometry (Appellants' claims 5, 6, 7, 10, 11 and 12).

The Examiner asserts that Shiiki et al. disclose that when the Tm of the polyglycolic acid is lowered, the processing temperature of the polymer can be lowered, therefore thermal decomposition upon melt processing can be reduced. Further, the Examiner asserts that Shiiki et al. disclose that the "stretch blow molding process" is a process in which stretching is conducted upon blow molding, thereby orienting the molecular chain of a polymer to enhance the physical properties of the polymer. The Examiner further states that in order to enhance such physical properties, it is essential to keep a parison at a temperature not higher than its melting point, but not lower than its glass transition point upon stretch blowing.

The Examiner admits that Shiiki et al. are silent with regards to the stretched product being obtained by stretching the glycolic acid homopolymer at 45-60°C at a stretching ratio exceeding 3x3 times, as required by Appellants' claims.

The Examiner asserts that Kawakami et al. disclose a stretch blow molding temperature of 30°C-100°C and a draw ratio in one direction of not higher than 10 times, preferably 1.5-5 times, and a blow-up ratio of 1.5-10 times.

The Examiner takes the position that it would have been obvious to substitute the stretch blow molding conditions of Kawakami et al. for the stretch blow conditions of Shiiki et al. The Examiner further asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to produce a container with optimal values of the crystal melting point, sub-dispersion peak temperature, main dispersion peak temperature, and the orientation degree since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Lastly, in the Advisory Action of September 16, 2010, the Examiner states that the patentability of the invention is based upon the product, not the process by which it was made, unless the end product has different properties than that of a product obtained in a different process. The Examiner further asserts that Appellants have not provided evidence to show that the stretching properties of Kawakami et al. using the composition of Shiiki et al. would not produce the same product as claimed by Appellants.

The Position of Appellants

Appellants respectfully disagree with the Examiner's positions described above.

Initially, neither Shiiki et al. nor Kawakami et al. teaches or suggests that an improvement in crystalline properties, as represented by an increase of at least 3°C in crystal melting point of a glycolic acid homopolymer, can be attained through **intense stretching as** represented by a combination of a low stretching temperature of 45°C-60°C and a large areal stretching ratio of at least 3×3 times.

The Examiner states that Shiiki et al. teach the necessity to keep a parison at a temperature not higher than its melting point (Tm), but not lower than its glass transition point (Tg) upon stretch blowing. The stretching temperatures of 45 - 80°C, adopted in Comparative Examples 1- 6 of the present application, are of course between Tm (of ca. 215- 220°C) and Tg (of ca. 38 °C, as indicated at page 11, lines 24 - 25 of the present application), as taught in [0052] of Shiiki et al., and are already much closer to Tg than Tm. However, these Comparative

Examples still failed to result in substantial intense stretching effects, as required by Appellants' claims. On the contrary, substantial intense stretching effects were obtained in Examples 1 - 4 of the present application, which adopted a combination of a lower temperature and a larger stretching ratio. Thus, regardless of whether Shiiki et al. suggest keeping a temperature between the melting point and the glass transition point, this would not lead one of ordinary skill in the art to arrive at Appellants' invention.

Although stretching has been known as a process for acting on an amorphous portion of a polymer, Appellants are unaware of any teaching that intense stretching of a crystalline polymer causes a remarkable increase in the crystalline melting point, as a representative crystalline property. Please see page 4, lines 20-24 of the specification.

The Examiner has failed to provide any reason as to why one skilled in this art would expect intense stretching to cause a remarkable increase in the crystalline melting point of polyglycolic acid. In fact, in the last paragraph on page 5 of the final Office Action, the Examiner takes the unsupported position that crystal melting point, sub-dispersion peak temperature, main dispersion peak temperature, and orientation degree are result effective variables. However, the Examiner has not provided any evidence to support this assertion, nor her position that it would be obvious to one of ordinary skill in the art to produce a container with optimal values for these specific properties. [Appellants presume that by "optimal values", the Examiner is implying those exact values recited in Appellants' claims.] Thus, the Examiner has failed to establish a *prima facie* case of obviousness, as supported by the following passages from the Manual of Patent Examining Procedure (MPEP).

MPEP 2144.03 states, "[w]hen the PTO seeks to rely upon a chemical theory, in establishing a prima facie case of obviousness, it must provide evidentiary support for the existence and meaning of that theory." *See In re Eynde*, 480 F.2d 1364, 1370 (CCPA 1973). Further, this section of the MPEP clarifies that, "[i]t is never appropriate to rely solely on 'common knowledge' in the art without evidentiary support in the record, as the principal evidence upon which a rejection was based.... [t]he Board cannot simply reach conclusions based on its own understanding or experience-or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings." *See In re Zurko*, 258 F.3d 1379, 1385-86 (Fed. Cir. 2001).

In this case, the Examiner has provided no evidentiary support regarding the assertion that one would optimize the specific properties of Appellants' claims, to arrive at the specific values recited in Appellants' claims. Furthermore, since neither reference teaches or suggests Appellants' recited crystalline properties, it is clear that the basis of the Examiner's rejection is the above-mentioned unsupported assertion.

As acknowledged by the Examiner, Shiiki et al. are silent with regards to the stretched product being obtained by stretching the glycolic acid homopolymer at 45-60°C at a stretching ratio exceeding 3x3 times. The Examiner asserts that the combination of Kawakami et al. and Shiiki et al. render Appellants' claims obvious. However, Appellants respectfully assert that, even if one of ordinary skill in the art were to combine the teachings of Shiiki et al. and Kawakami et al. as suggested by the Examiner, they would still fail to arrive at Appellants' invention. Specifically, Kawakami et al. fail to teach or suggest Appellants' claimed product, or the process steps recited in Appellants' claims. On the contrary, Kawakami et al. merely teach broad ranges for temperature (30-100°C) and stretching ratios (draw ratio higher than one but not higher than 10 in a machine direction, and blow up ratio of 1.5-10). Appellants respectfully assert that these general ranges of Kawakami et al. do not remedy the deficiencies of the Shiiki et al. reference, and would not render Appellants' claimed product obvious to one of ordinary skill in the art.

Furthermore, even if a *prima facie* case of obviousness is deemed to have been established by the Examiner, Appellants have rebutted any such case of obviousness by demonstrating the criticality of Appellants' recited range. As discussed in MPEP 2144.05, "The law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims. . . . In such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range." *See In re Woodruff*, 919 F.2d 1575 (Fed. Cir. 1990).

Appellants respectfully direct the Board's attention to the Examples and Comparative Examples of the specification. Table 1 (page 24 of the specification) demonstrates that the stretched films of Comparative Examples 1-3, which were obtained through stretching at ratios of 3 x 3 times at 45-80 °C, and the stretched films of Comparative Examples 4 and 5, which were

obtained through stretching at ratios of 4 x 4 times or 4.5 x 4.5 times, respectively, caused an increase in the crystal melting point (Tm) of **only 1-2** °C compared to Comparative Example 6, which is unstretched. On the contrary, Examples 1-4, which were obtained through stretching at ratios of 4 x 4 or 4.5 x 4.5 times, at a stretching temperature of 45 or 60 °C, **exhibited an extremely remarkable increase in Tm of 8-9**°C **compared to Comparative Example 6** (unstretched).

Thus, Examples 1-4 fulfill the requirement of Appellants' claim 1, i.e., that the stretched product has a Tm higher by **at least 3** °C than the unstretched product. On the contrary, Comparative Examples 1-5 fail to full this requirement.

Furthermore, in Example 4 of Shiiki et al. (the only example of a cold stretch blow molding process for PET/Adh/PGA/Adh/PET laminate in the reference), a stretched temperature of about 85°C and a stretching ratio of 3 x 2 times is used. Appellants note that the temperature is higher than the highest temperature in the Comparative Examples of the specification (i.e., 80°C), and the ratio is smaller than the smallest stretching ratio in the Comparative Examples of the specification (i.e., 3 x 3 times).

Thus, in view of the comparison discussed above (based upon the experiments in Appellants' specification), one of ordinary skill in the art would not expect the teachings of Shiiki et al. to result in the stretched product of Appellants' claims.

Moreover, the stretching conditions adopted in Example 1 of Kawakami et al., including a stretch temperature of 45°C and a stretch ratio of about 2.25 times in a machine direction and a blow-up ratio of about 2.8, giving an areal stretch ratio of about 6.3 (=2.25×2.8), are **substantially milder** than 45°C and an areal stretch ratio of 9 (=3×3) times adopted in Comparative Example 1, which provided an increase in crystalline melting temperature of **only 2°C** (=218°C–216°C, as compared with the un-stretched film of Comparative Example 6) in the present specification.

Accordingly, it would have been unobvious for one of ordinary skill to arrive at an increase in crystal melting point of at least 3°C as an optimum value of a result effective variable by varying stretching conditions based on the teachings of Shiiki et al. and Kawakami et al., since these references fail to even teach or suggest that modification of crystal properties of glycolic acid homopolymer (PGA) can be obtained by varying stretching conditions. As

discussed above, the Examiner has provided no support regarding her assertion that determining optimal values of crystal melting point, sub-dispersion peak temperature, main dispersion peak temperature, and orientation degree would have been obvious. Accordingly, this assertion must be based only on the readings of Appellants' disclosure. The Examiner has provided no other basis for why one would alter the teachings of the references in the manner suggested. As stated by the Supreme Court in KSR International Co. v. Teleflex Inc., "the factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning." See KSR International Co. v. Teleflex Inc., 127 S. Ct. 1727 (U.S. 2007), referring to Graham v. John Deere Co. of Kansas City, 86 S. Ct. 684, which warned against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "guard against slipping into the use of hindsight".

In the Advisory Action dated September 16, 2010, Examiner states that the claims are in product by process form, and the patentability is based on the product rather than the process, unless the end product has different properties than a product made by a different process. However, Appellants kindly note that such evidence has previously been provided. Such evidence is discussed in detail above.

In the Advisory Action, the Examiner also states, "It is the examiner's position that the arguments provided by the applicant regarding that the intense stretching of the PGA product leads to the increase in the crystal melting point must be supported by a declaration or affidavit." However, on September 26, 2008, Appellants submitted a Declaration Under 37 CFR § 1.132 (by Naoko Hamada) which recites "The invention of the instant application … is based on the discovery that only intense stretching, i.e., at a large stretching ratio and at a temperature not substantially higher than a glass transition temperature (Tg) of a crystalline aliphatic polyester, results in the characteristic effects of the instant invention." The following is the relevant excerpt from the Declaration:

6. The invention of the instant application (hereinafter referred to as the instant invention) is based on the discovery that only intense stretching ,i.e., at a large stretching ratio and at a temperature not substantially higher than a glass-transition temperature (Tg) of a crystalline aliphatic polyester, results in the characteristic effects of the instant invention, i.e., a substantial increase in crystal melting point, main and sub-dispersion peak temperature according to dynamic viscoelasticity measurement, which lead to substantial improvements in retort-durability, gas-barrier property and impact strength. This is already believed to be clearly demonstrated for polyglycolic acid (PGA) by comparison between Examples 1-4 and Comparative Examples 1-6 in Tables 1-2 at page 24 of the instant application. Thus, the intense stretching effects could only be attained by stretching at a large ratio exceeding 3x3 times and at temperatures of $45-60^{\circ}$ C, which are not substantially above the Tg (= $38-40^{\circ}$ C) but much lower than the melting point (Tg = $215-220^{\circ}$ C) of PGA.

Thus, Appellants have previously provided the very evidence which is now requested by the Examiner. (Tables 1 and 2 from the originally filed specification are provided below for convenience.)

Table 1

Example	Stretching		Crystal melting point	Wide angle X-ray diffraction	Dynamic viscoelasticity measurement		Anti-impact strength	
	temp (°C)	ratio (times)	Tm (°C)	Orientation deg. (%)	Main dispersion peak temp. (°C)	Sub- dispersion peak temp. (°C)	Force (N)	Energy (J)
1	45	4.0×4.0	224	85	67	-45	285	1.21
2	45	4.5×4.5	225	84	70	-45	238	0.92
3	60	4.0×4.0	225	85	70	-44	146	0.63
4	60	4.5×4.5	225	84	71	-43	195	0.77
Comp. 1	45	3.0×3.0	218	82	63	-47	101	0.40
Comp. 2	60	3.0×3.0	216	81	67	-48	49	0.21
Comp. 3	80	3.0×3.0	217	84	64	-48	76	0.25
Comp. 4	80	4.0×4.0	217	81	70	-49	112	0.43
Comp. 5	80	4.5×4.5	217	82	69	-48	64	0.20
Comp. 6	-	unstretched	216	0	45	-49	5	0.01

Table 2

Example	Stretch	ing	Oxygen permeability (PO ₂)*			
•	temp (°C)	ratio (times)	Before retorting	After retorting at 105 ℃	After retorting at 120 ℃	
1	45	4.0×4.0	1.3×10^{-14}	2.8×10^{-14}	7.3×10^{-14}	
2	45	4.5×4.5	1.1×10^{-14}	3.0×10^{-14}	8.0×10^{-14}	
3	60	4.0×4.0	1.1×10^{-14}	2.8×10^{-14}	6.0×10^{-14}	
4	60	4.5×4.5	1.2 × 10 ⁻¹⁴	3.0×10^{-14}	8.8 × 10 ⁻¹⁴	
Comp. 1	45	3.0×3.0	1.7×10^{-14}	2.7×10^{-14}	68 × 10 ⁻¹⁴	
Comp. 2	60	3.0×3.0	2.2×10^{-14}	2.7×10^{-14}	14 × 10 ⁻¹⁴	
Comp. 3	80	3.0×3.0	1.7×10^{-14}	3.0×10^{-14}	20× 10 ⁻¹⁴	
Comp. 4	80	4.0×4.0	2.3×10^{-14}	4.3×10^{-14}	18 × 10 ⁻¹⁴	
Comp. 5	80	4.5×4.5	1.4 × 10 ⁻¹⁴	7.5×10^{-14}	36 × 10 ⁻¹⁴	
Сотр. б	-	unstretched	7.8×10^{-14}	**	**	

Lastly, in the Advisory Action, the Examiner asserts that Appellants have not provided evidence to show that the stretching properties of Kawakami et al. using the composition of Shiiki et al. would not produce the same product as claimed by Appellants. Appellants traverse this position of the Examiner for two reasons.

First, as discussed previously, Appellants have presented comparative experiments in the specification, and have demonstrated that stretching conditions which are closer to Appellants' claims (Comparative Example 1) than the example in Kawakami et al. do not result in a product

according to Appellants' claims. Thus, the results of Kawakami et al. would be even more remote from the requirements of Appellants' invention. In this regard, MPEP 716.02(e) confirms that "Applicants may compare the claimed invention with prior art that is more closely related to the invention than the prior art relied upon by the examiner. *In re Holladay*, 584 F.2d 384, 199 USPQ 516 (CCPA 1978); *Ex parte Humber*, 217 USPQ 265 (Bd. App. 1961)."

Second, this comparison is not required in order to show the unobviousness of Appellants' invention. Specifically, MPEP 716.02(e) states that "[a]lthough evidence of unexpected results must compare the claimed invention with the closest prior art, applicant is not required to compare the claimed invention with subject matter that does not exist in the prior art. *In re Geiger*, 815 F.2d 686, 689, 2 USPQ2d 1276, 1279 (Fed. Cir. 1987) (Newman, J., concurring) ... Requiring applicant to compare claimed invention with polymer suggested by the combination of references relied upon in the rejection of the claimed invention under 35 U.S.C. 103 'would be requiring comparison of the results of the invention with the results of the invention." *See In re Chapman*, 357 F.2d 418, 422 (CCPA 1966).

Accordingly, the rejection of claims 1-7 and 10-12 as being unpatentable over Shiiki et al. and Kawakami et al. is untenable for the reasons provided above.

Conclusion

For the foregoing reasons, the invention of claims 1-7 and 10-12 is patentable over the combination of references relied upon by the Examiner. Thus, reversal of the final rejection is respectfully requested.

Attached hereto are a Claims Appendix, an Evidence Appendix and a Related Proceedings Appendix.

The brief is submitted with the required fee.

Respectfully submitted,

Daisuke ITOH, et al.

/Amy E. Schmid/ By2011.01.13 09:56:42 -05'00'

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VIII. CLAIMS APPENDIX

- 1. (Appealed) A stretched product of crystalline aliphatic polyester, having a crystal melting point higher by at least 3°C than that of an unstretched product thereof, wherein said crystalline aliphatic polyester is glycolic acid homopolymer, and wherein the stretched product is obtainable by stretching the glycolic acid homopolymer at 45-60°C at a stretching ratio exceeding 3×3 times.
- **2. (Appealed)** A stretched product according to Claim 1, having a crystal melting point higher by at least 5°C than that of the unstretched product thereof.
- **3. (Appealed)** A stretched product of crystalline aliphatic polyester according to Claim 1, showing a sub-dispersion peak temperature of at least –46°C according to dynamic viscoelasticity measurement in at least one direction thereof.
- **4. (Appealed)** A stretched product according to any one of Claims 1 and 3, showing a main dispersion peak temperature of at least 67°C according to dynamic viscoelasticity measurement in at least one direction thereof.
- **5. (Appealed)** A stretched product according to any one of Claims 1 and 3, showing an orientation degree of at least 83 % as measured according to wide-angle X-ray diffractometry in at least one direction thereof.
- **6. (Appealed)** A stretched product of crystalline aliphatic polyester according to Claim 1, showing a main dispersion peak temperature of at least 67°C according to dynamic viscoelasticity measurement in at least one direction thereof and an orientation degree of at least 83 % according to wide-angle X-ray diffractometry in at least one direction thereof.
- **7. (Appealed)** A stretched product according to any one of Claims 1, 3 and 6, satisfying the prescribed property in both of longitudinal and transverse directions thereof.

8-9. (Cancelled)

- **10. (Appealed)** A stretched product according to any one of Claims 1, 3 and 6, having a form of film.
- **11. (Appealed)** A stretched product according to any one of Claims 1, 3 and 6, having a form of bottle.
- **12. (Appealed)** A stretched product according to any one of Claims 1, 3 and 6, having a laminate form including a layer of the stretched aliphatic polyester and another polymer layer disposed in lamination.

IX. EVIDENCE APPENDIX

None

X. RELATED PROCEEDINGS APPENDIX

None